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Pendlebury

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(54) **STEM CELL DELIVERY DEVICE FOR ORTHOBIOLOGICS APPLICATIONS**

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A61M 5/44 (2006.01)
A61M 5/28 (2006.01)
A61M 5/32 (2006.01)

(52) **U.S. Cl.**

CPC *A61M 5/445* (2013.01); *A61M 5/282* (2013.01); *A61M 5/3298* (2013.01); *A61M 2205/3653* (2013.01); *A61M 2205/8206* (2013.01)
USPC 604/113; 604/114; 604/291; 604/522

(58) **Field of Classification Search**

CPC A61M 5/44; A61M 5/445; A61M 1/025; A61M 2205/8206

USPC 604/290, 291, 506, 522, 113, 114
See application file for complete search history.

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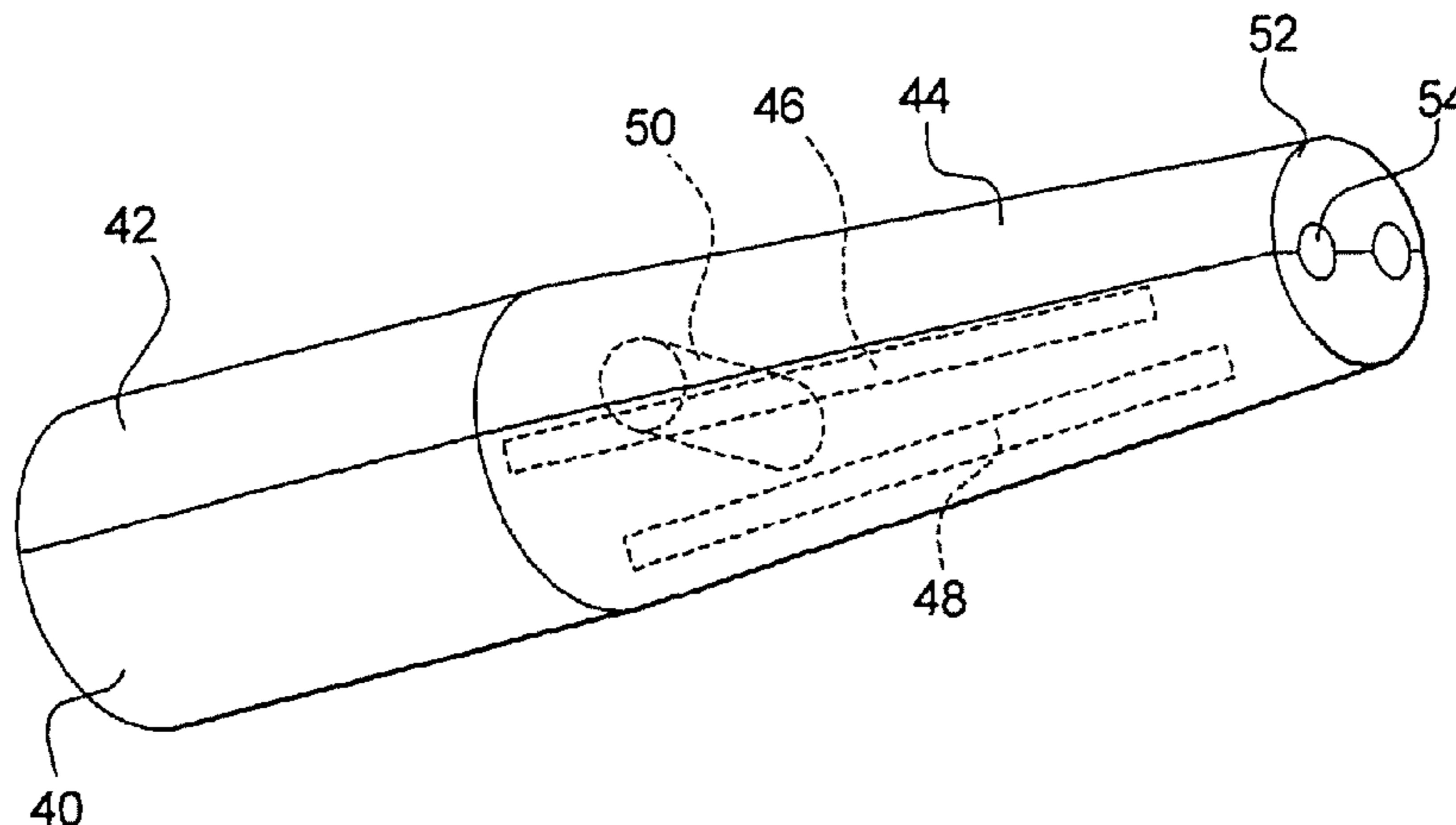
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(57) **ABSTRACT**

A method and apparatus for thawing and delivery of cryogenically frozen biological material, such as stem cells includes a housing for receiving a pouch of frozen cells, a heating element against which the pouch is placed for applying defrosting heat to the pouch, and a squeezing apparatus for applying a squeezing force to the pouch after or upon thawing of the cells. The squeezing force may be applied by a roller pressing the pouch against the heating element, which forces the thawed cells from a needle or tube connected to the housing and/or to the pouch. A rechargeable battery in the housing supplies power to the heating element and the squeezing apparatus.

8 Claims, 7 Drawing Sheets



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FIG. 1

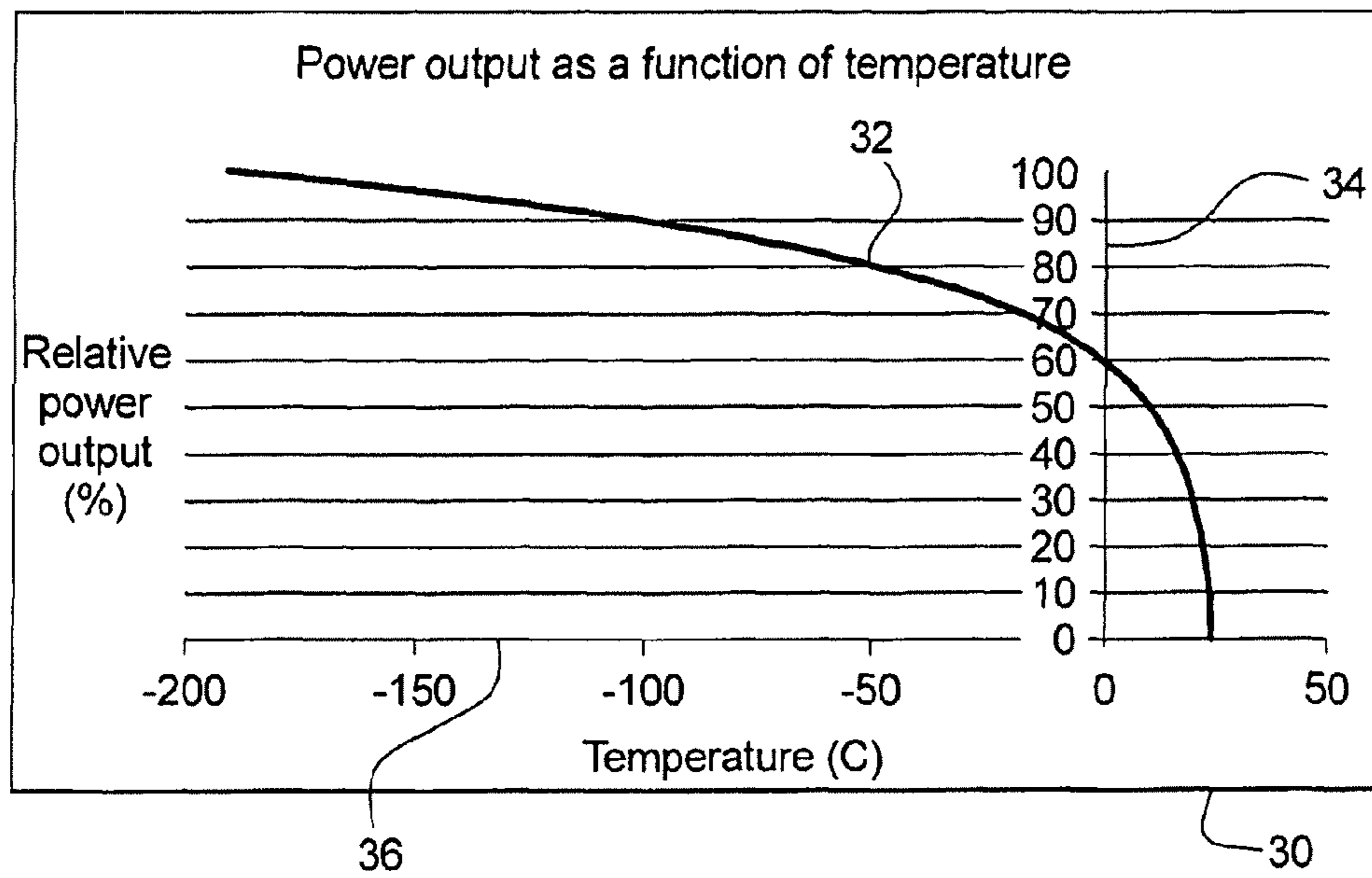


FIG. 2

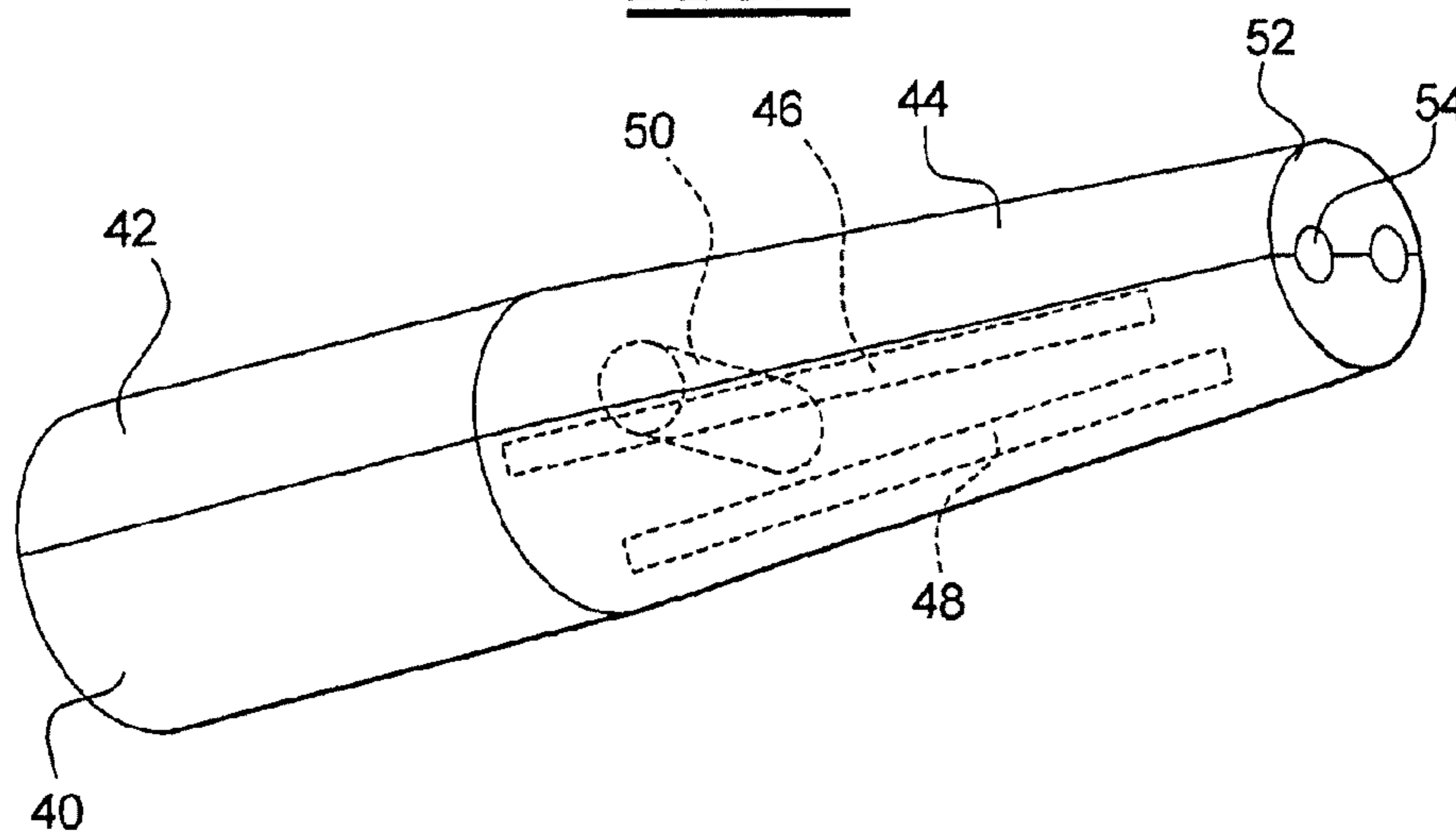


FIG. 3

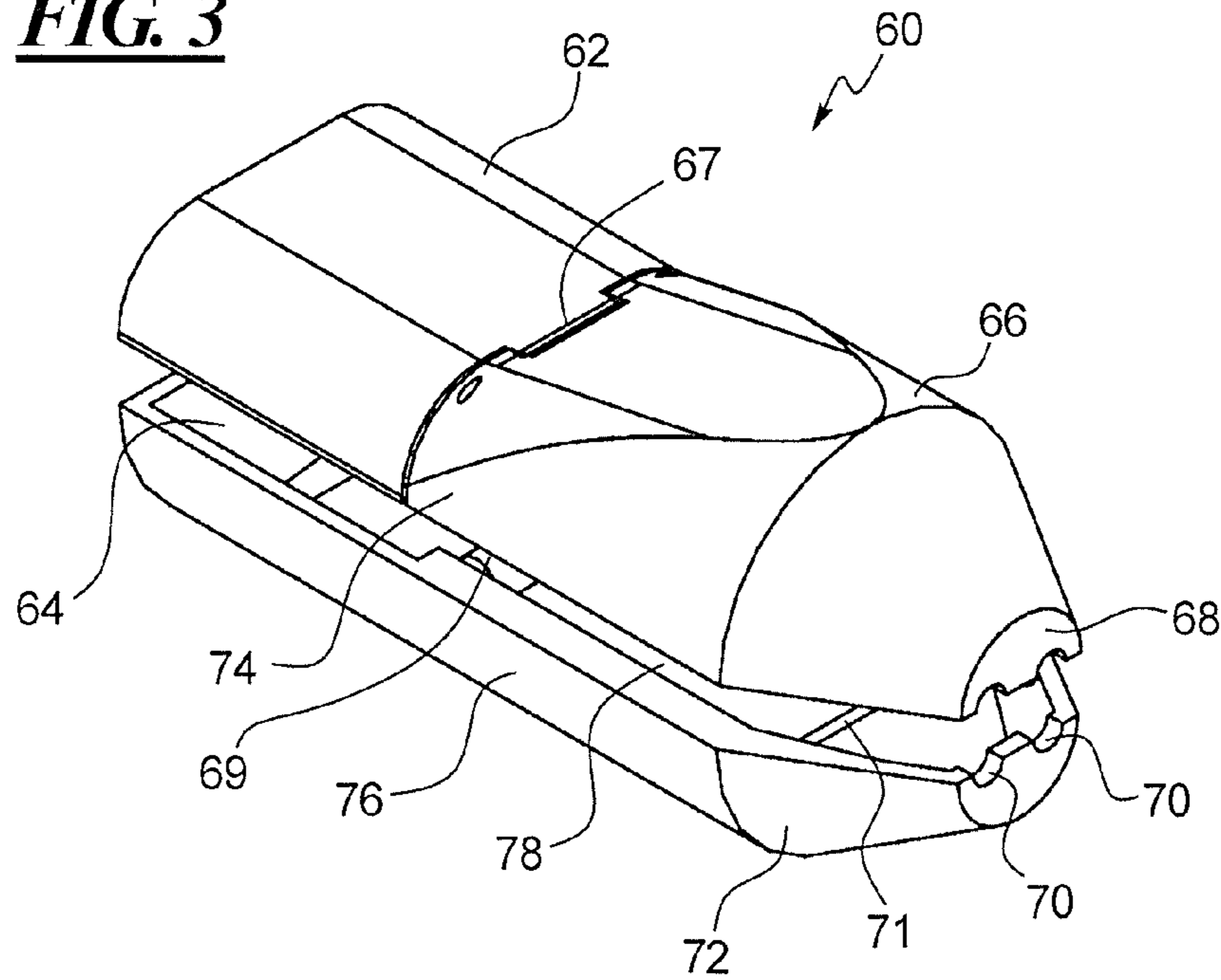
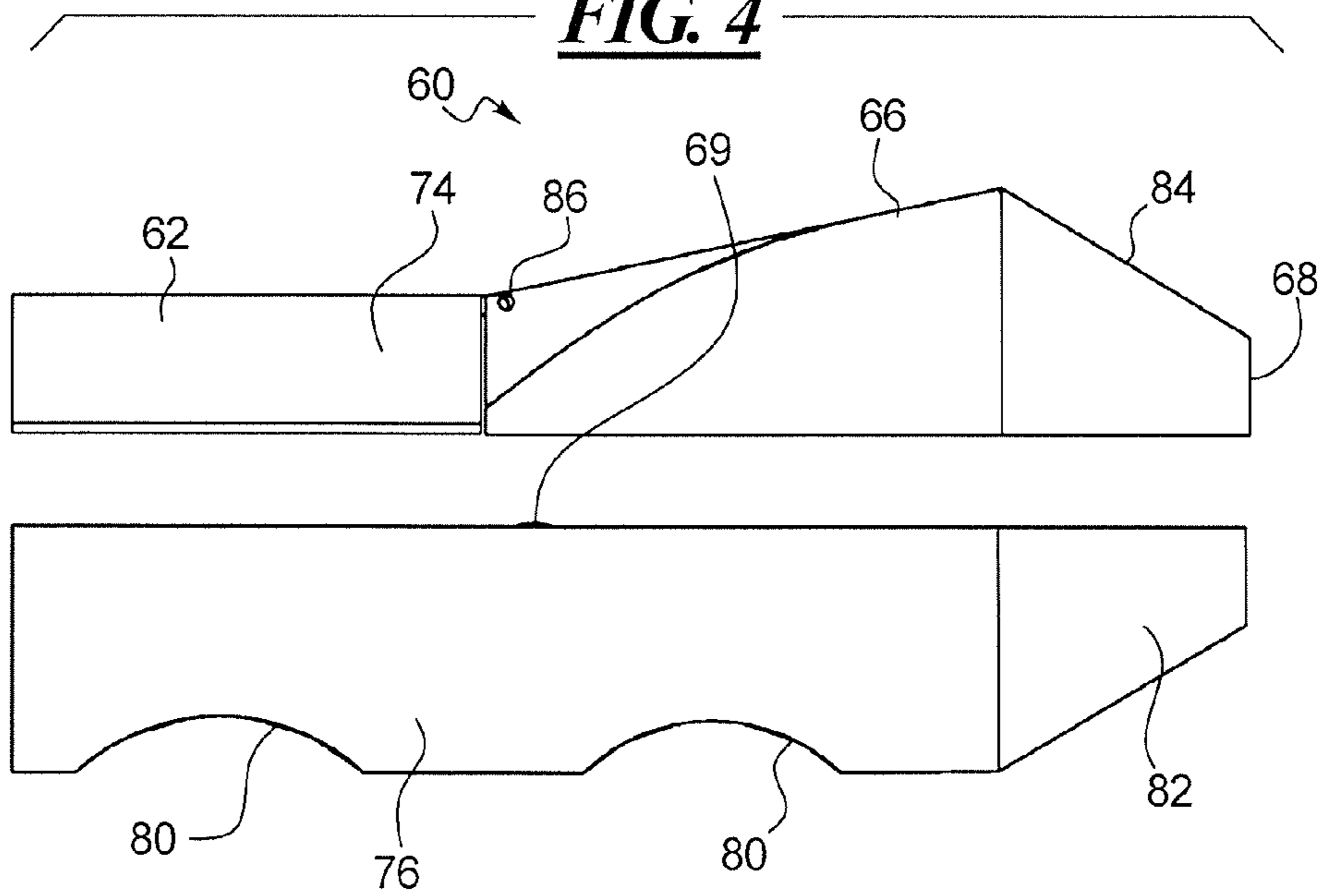
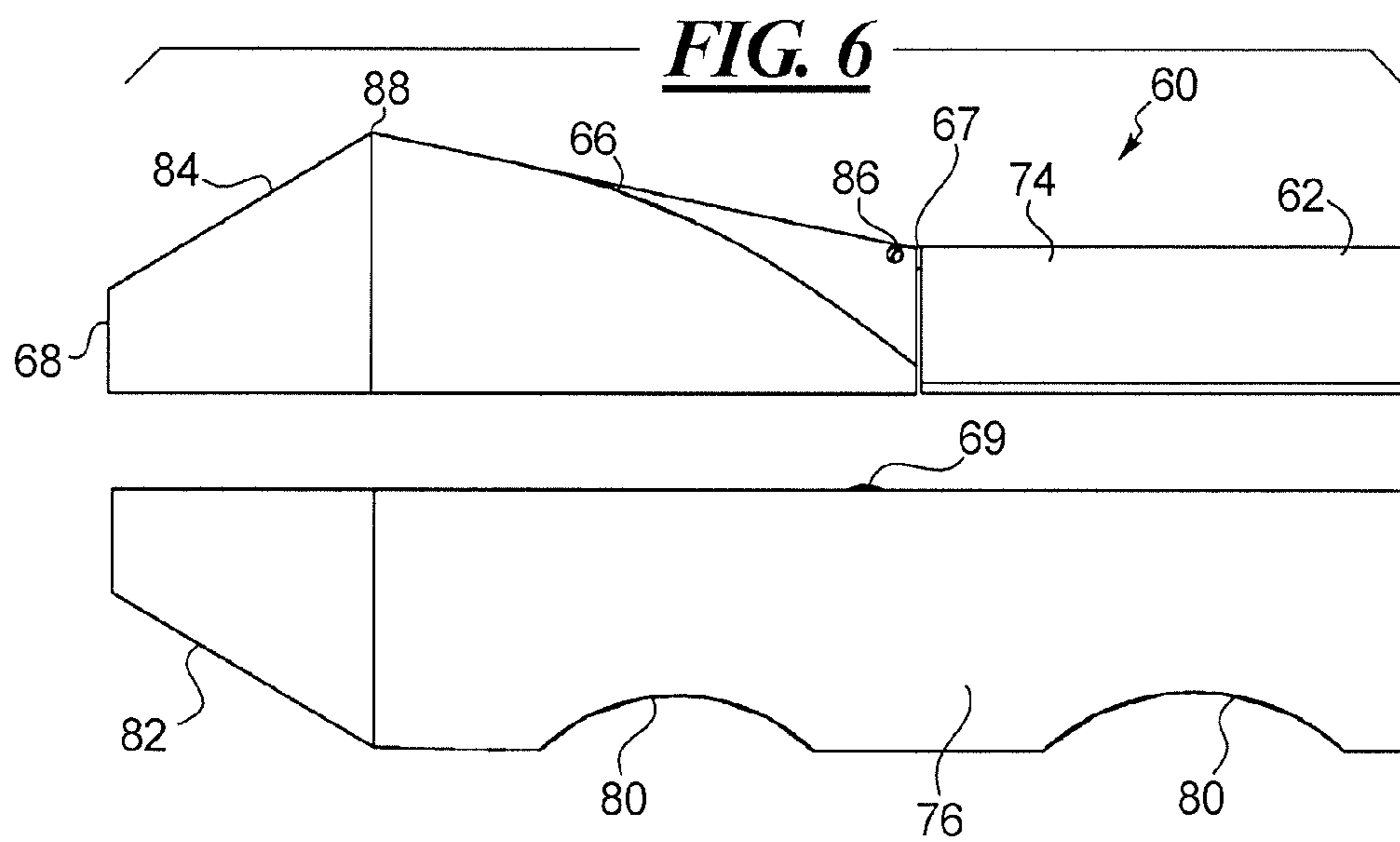
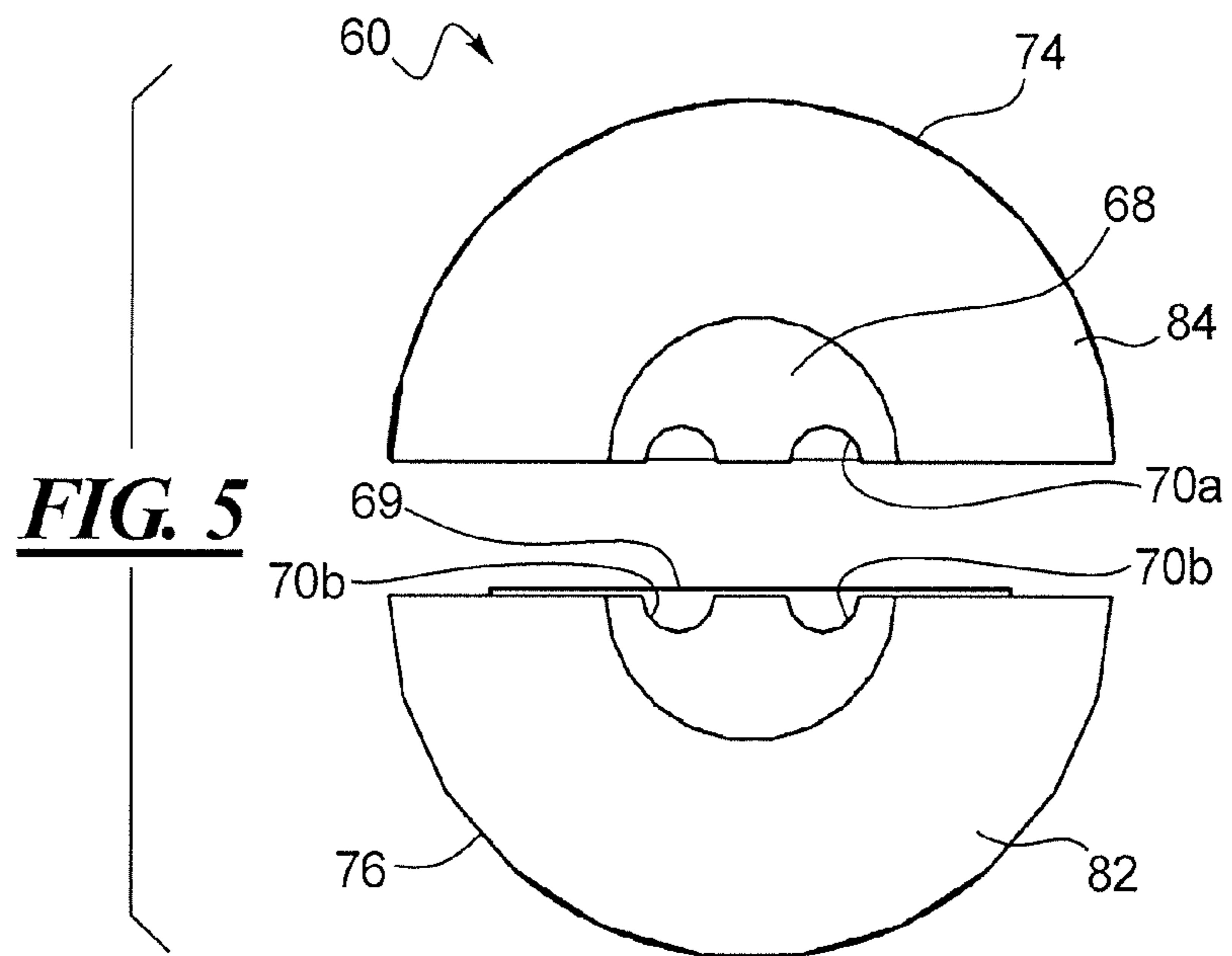


FIG. 4





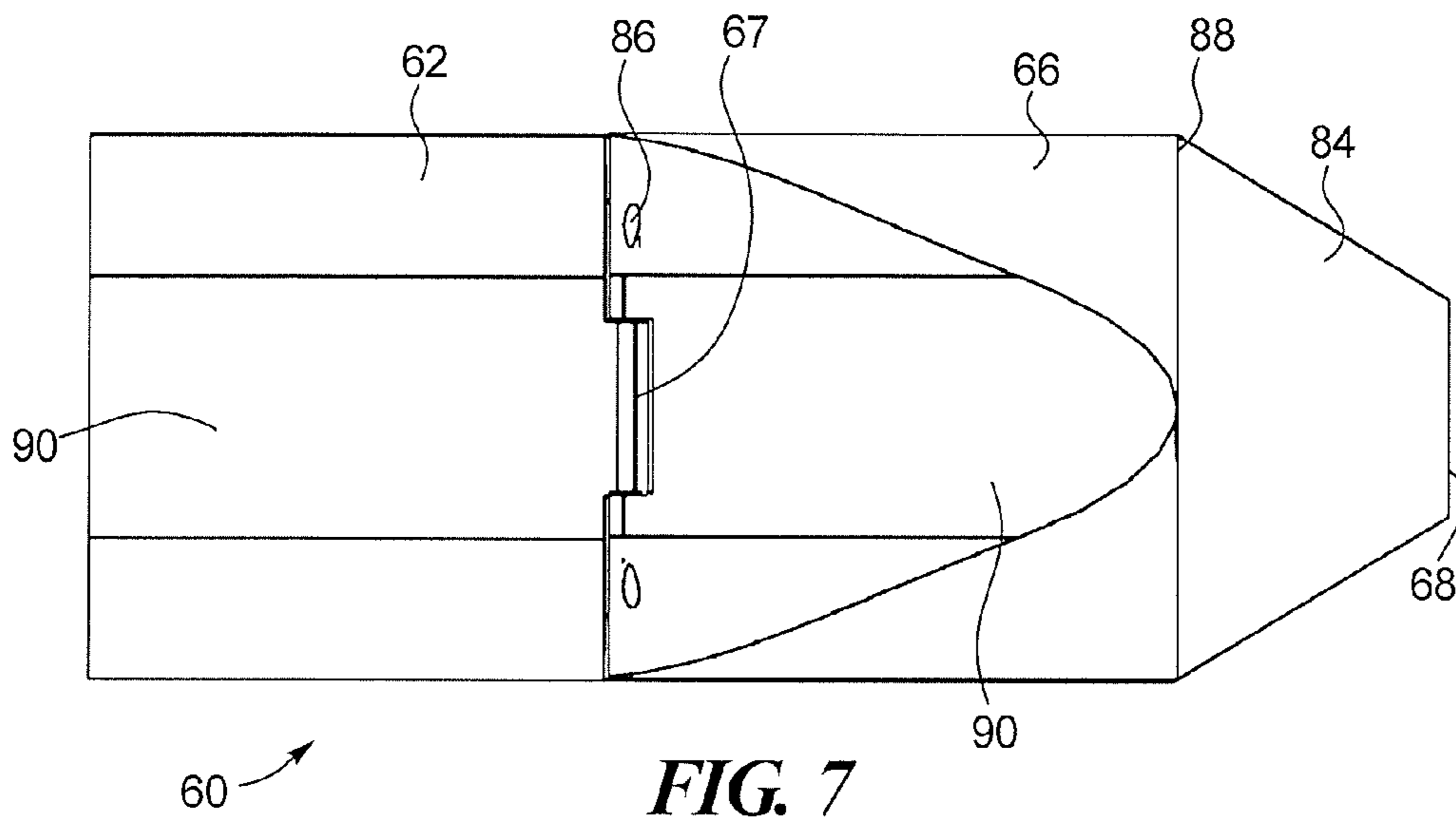


FIG. 7

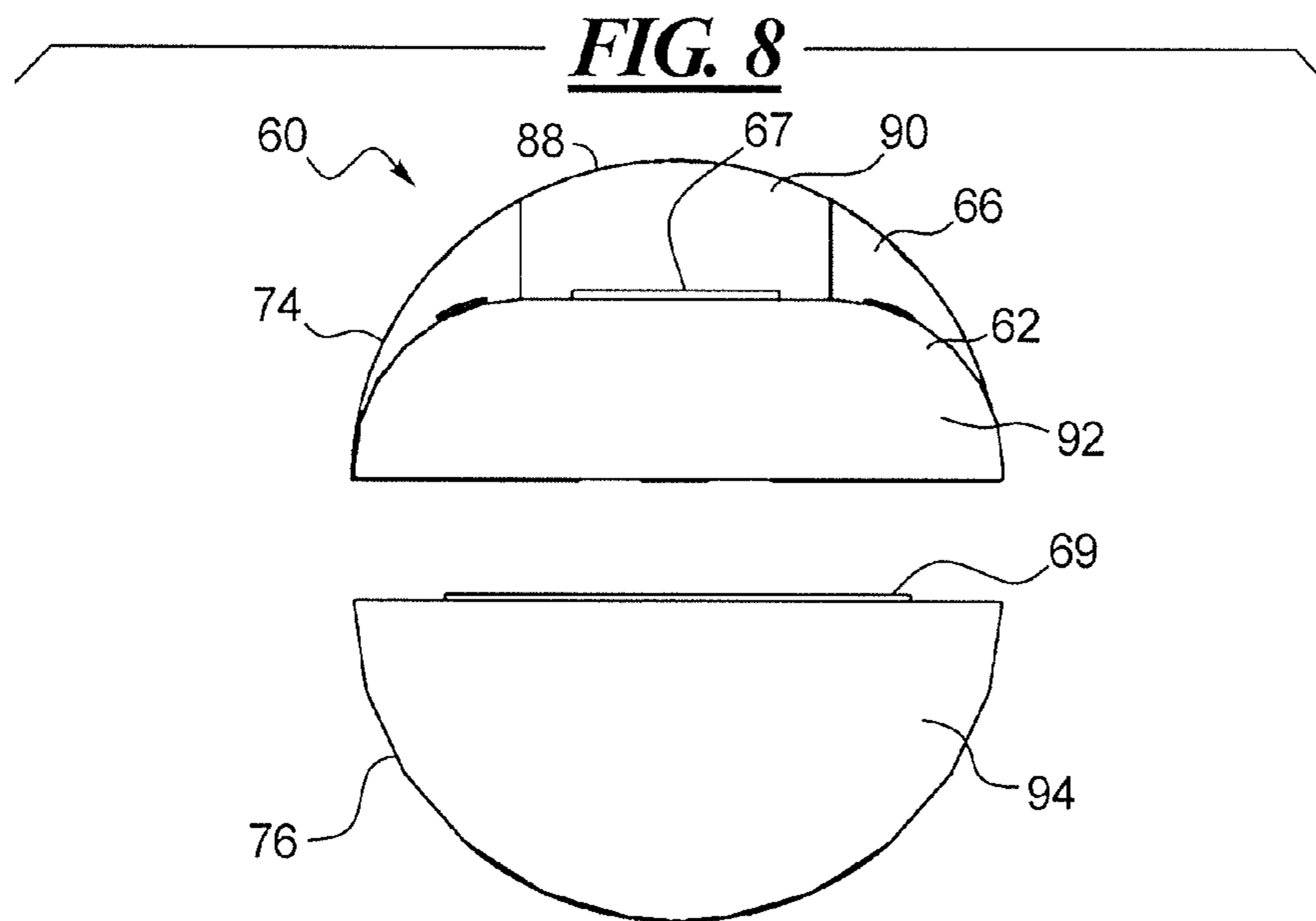


FIG. 8

FIG. 9

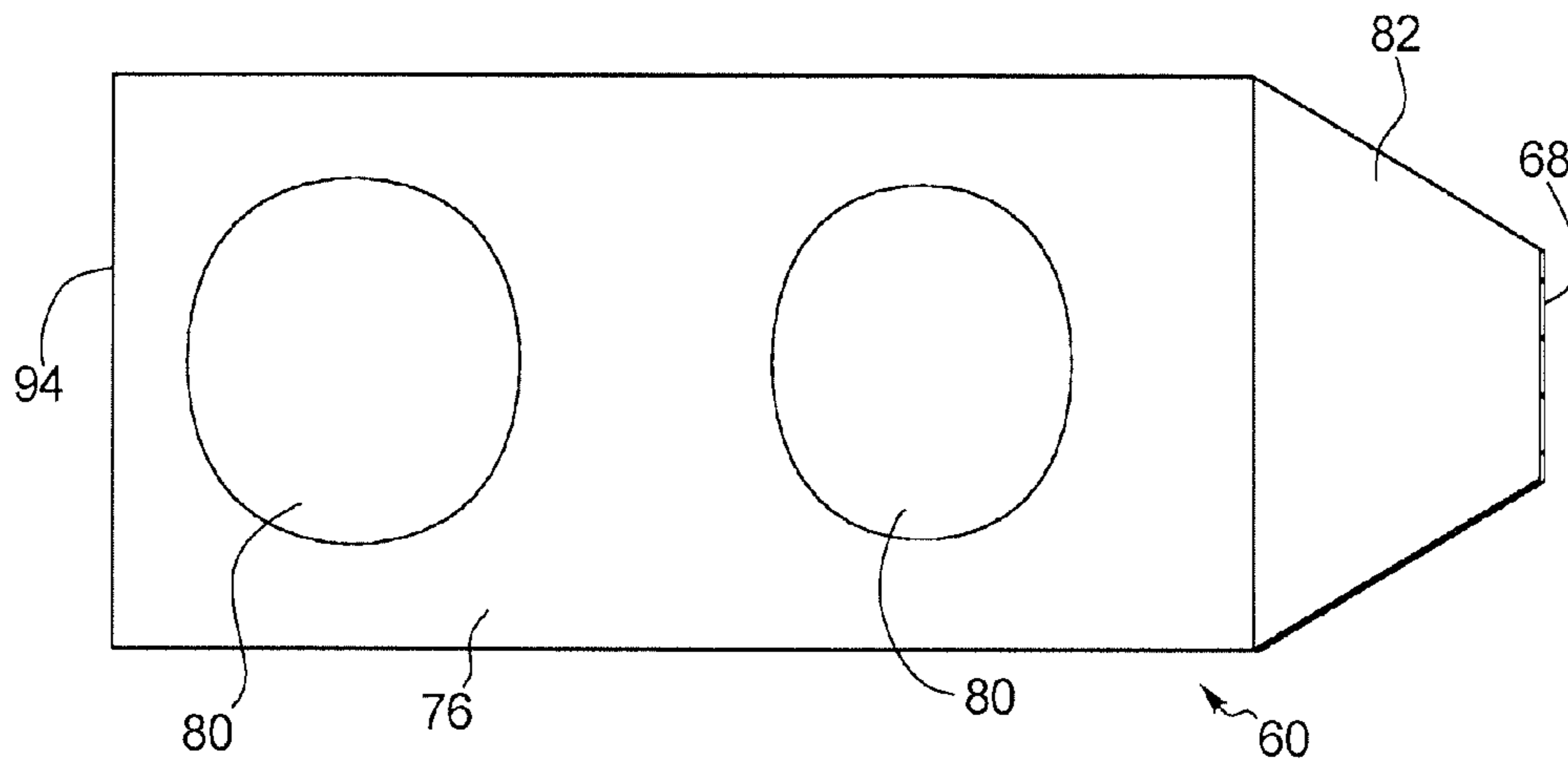


FIG. 10

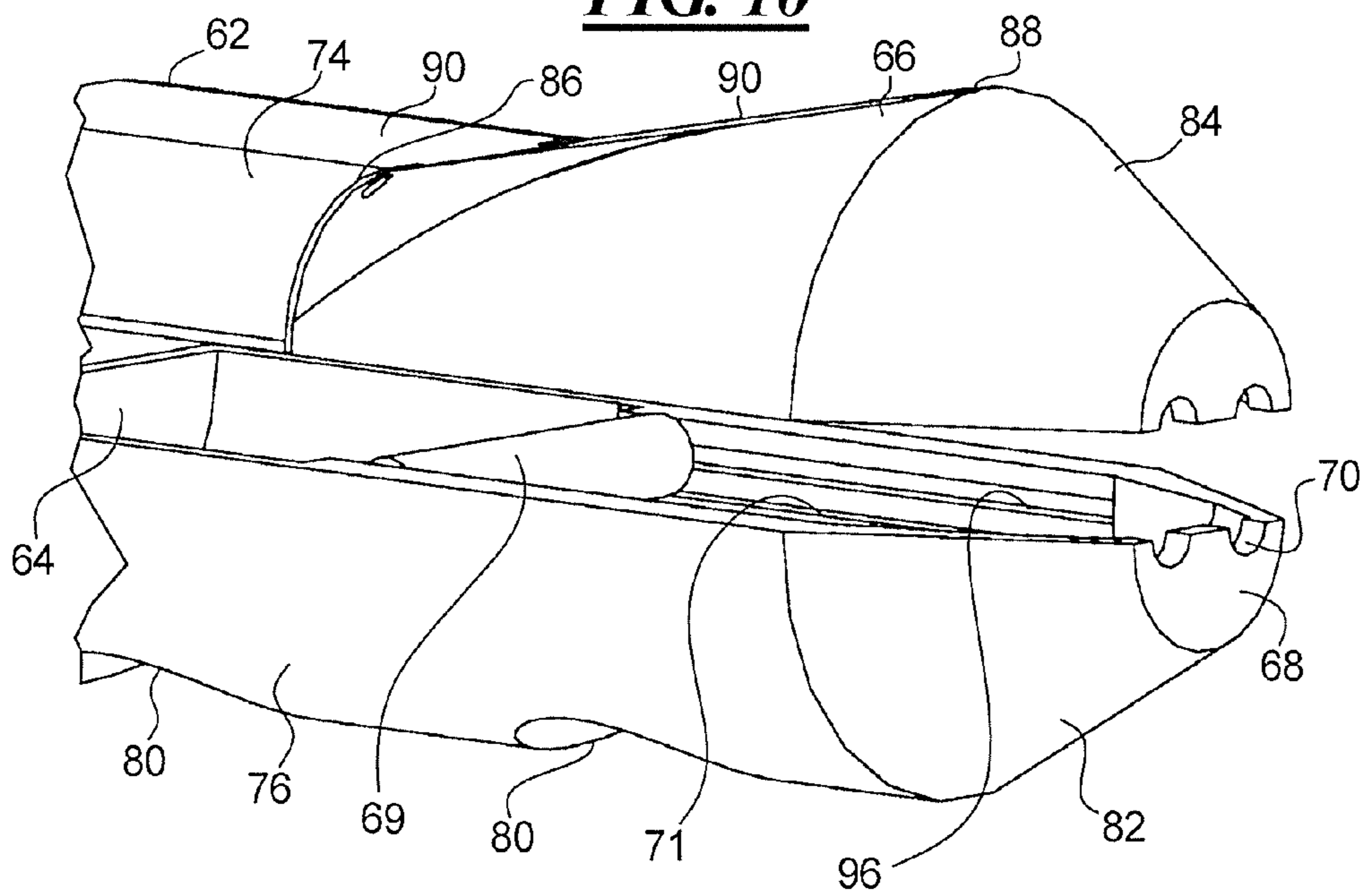


FIG. 12

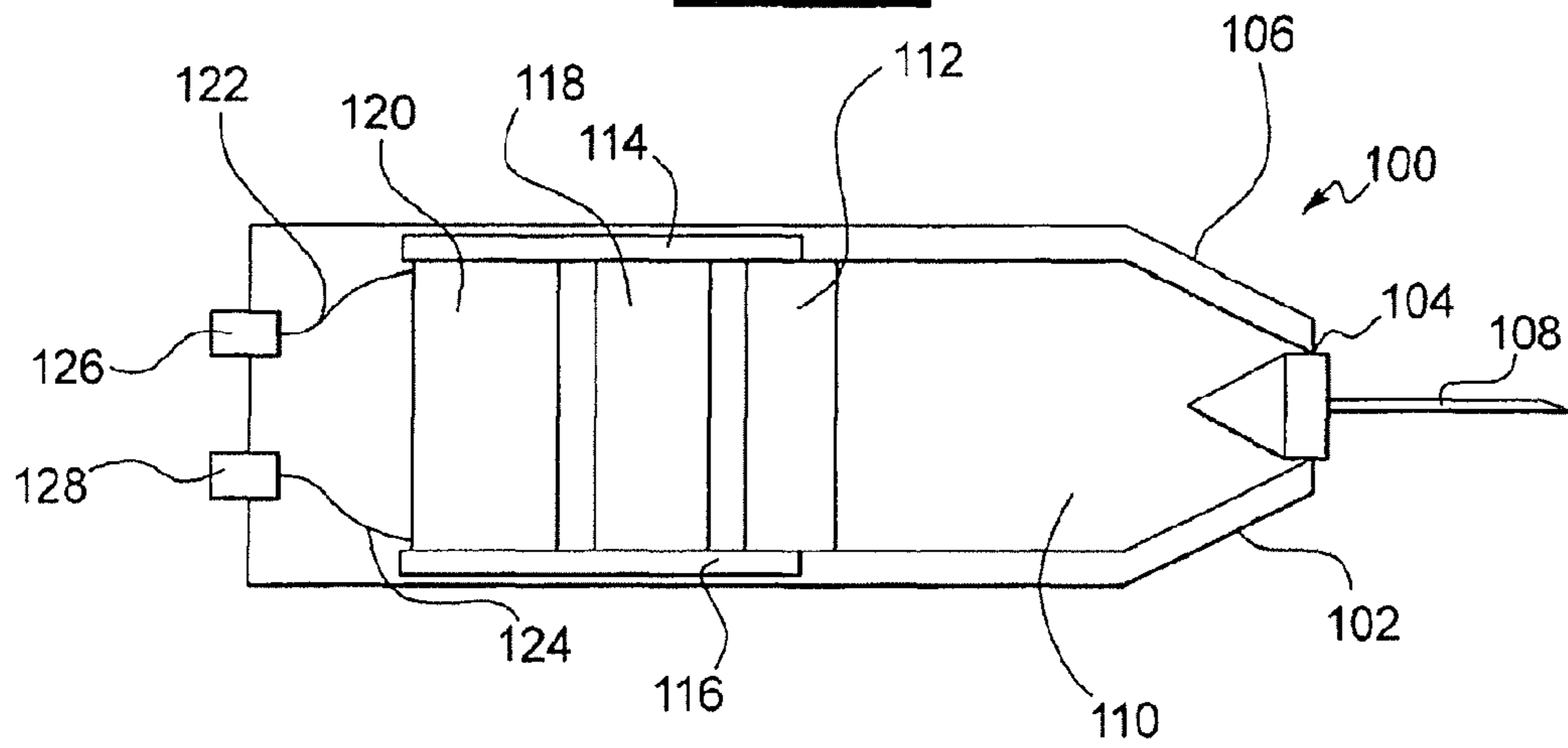
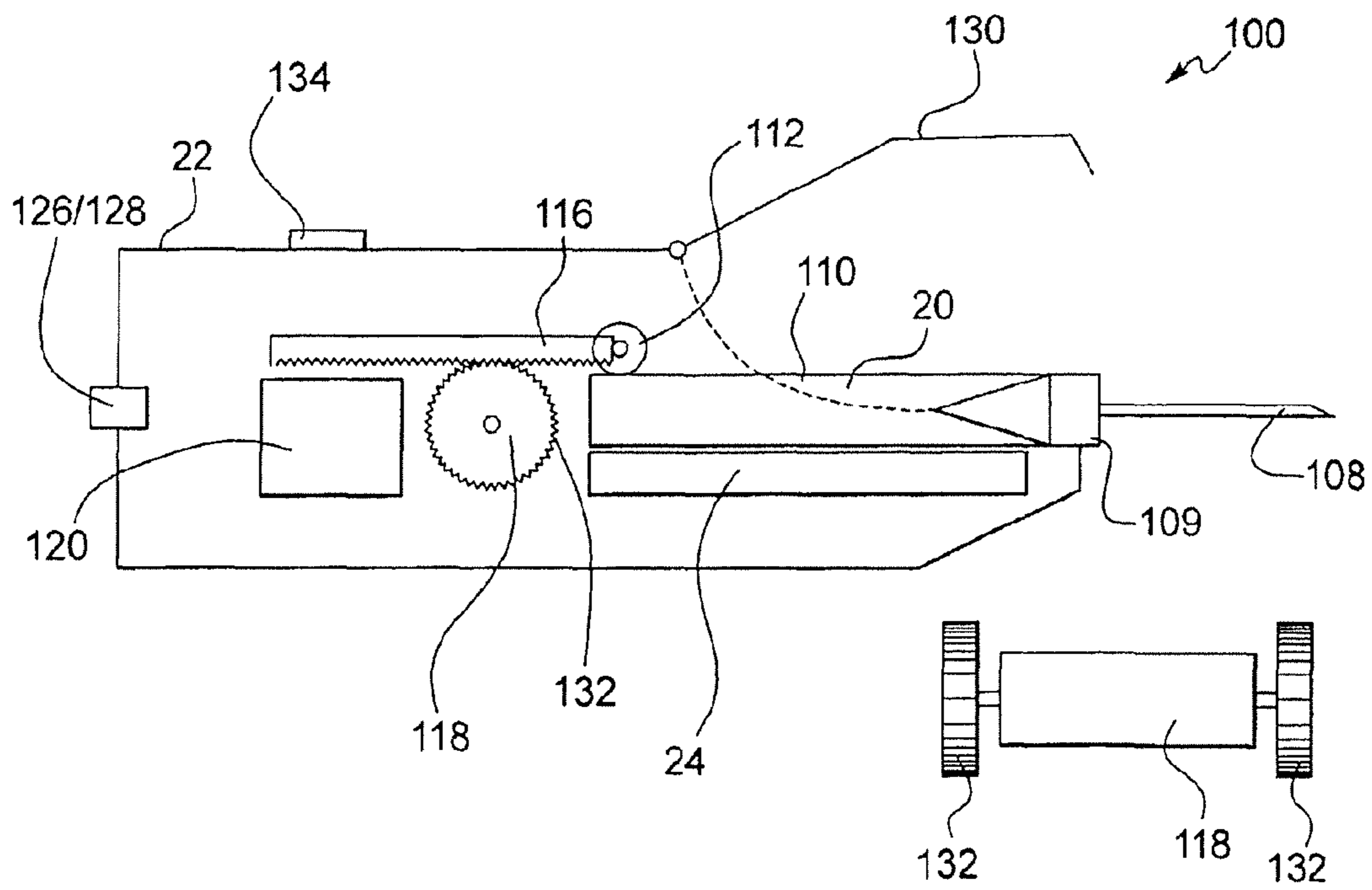


FIG. 13



STEM CELL DELIVERY DEVICE FOR ORTHOBIOLOGICS APPLICATIONS

CROSS-REFERENCE TO RELATED APPLICATION

This application claims the benefit of U.S. Provisional Patent Application Ser. No. 61/187,013, filed Jun. 15, 2009, which is incorporated by reference herein.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to a device and method for warming frozen cells and other biological materials and in particular to a delivery device and method for thawing and squeezing pouches of frozen cells.

2. Description of the Related Art

Stem cells are cells which are capable of differentiating into other cells depending upon their environments. For example, hematopoietic cells transform into cells found in blood and bone marrow, endolethial stem cells transform into cells associated with the vascular system, such as veins and arteries, while mesenchymal stem cells form bone, cartilage, muscle and fat. These cells are generally stored in a cryogenically frozen condition. In order to use these cells in a clinical environment, they have to be defrosted or thawed. Defrosting or thawing must be performed using a particular thermal profile to avoid damage to the cells by the formation of ice crystals. This generally requires that the defrosting of the cells take place in a thawing apparatus to control the temperature profile. In one example, the thawing of the stem cells prior to injection is usually done in a water bath which is set at a temperature of 37 degrees C. and takes around 3-4 minutes for a 5 ml vial. For pouches of frozen cells, prior solutions involve thawing out the pouches of stem cells in a water bath, set at a temperature of 37 C, for about 5 minutes. After the cells are thawed, the defrosted cells are placed in a device suitable for the delivery of the cells to the target site. For vascular applications, the incorporation of stem cells onto stents has been described but for orthopaedic treatments, the stem cells are typically injected using standard arthroscopic procedures.

SUMMARY OF THE INVENTION

The present device and method solves the problem of how to inject stem cells into the body without having to thaw the cells first in an external apparatus and then transfer them to a delivery device. A delivery device is provided that includes a warming element to apply heat to a container of frozen cells and includes an apparatus to apply a force to the container to deliver the cells as they are thawed. In particular, a pouch containing frozen stem cells is placed into the delivery device in thermal contact with a heating element that is mounted within the delivery device. A conduit, tube, needle or other carrier device is connected to the pouch, or is already provided on the pouch. The heating element is operated to heat the pouch according to a thawing profile to thereby thaw the frozen cells. A squeezing apparatus is provided in the delivery device to squeeze the pouch and deliver the thawed cells through the conduit, tube, needle or other carrier device. The frozen cells are both thawed and delivered by the same device so that the use of ancillary equipment is not required to thaw out the stem cells for delivery.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a graph of power output as a function of temperature for a thermoelectric device in the present stem cell delivery device;

FIG. 2 is a sketch of the present device including descriptive text;

FIG. 3 is a top perspective view of a stem cell delivery device according to the principles of the present invention, shown with the two halves of the device separated for purposes of illustration;

FIG. 4 is a side elevational view of the stem cell delivery device of FIG. 3, shown with the two halves separated for purposes of illustration;

FIG. 5 is an end elevational view of the stem cell delivery device, shown with the two halves of the device separated;

FIG. 6 is a side elevational view of the stem cell delivery device shown from the opposite site as compared to FIG. 4, shown with the two halves separated;

FIG. 7 is a top plan view of the stem cell delivery device;

FIG. 8 is an end elevational view of the stem cell delivery device from the opposite end as compared to FIG. 5, shown with the two halves of the device separated;

FIG. 9 is a bottom plan view of the stem cell delivery device;

FIG. 10 is an enlarged front perspective view of the open stem cell delivery device showing the interior of the device;

FIG. 11 is an enlarged end perspective view of the stem cell delivery device;

FIG. 12 is a plan view of the interior of the delivery device to which is attached a delivery needle; and

FIG. 13 is a side cross sectional view of the delivery device to which is attached a delivery needle and within which is a pouch of frozen stem cells.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

When manufactured or prepared, stem cells and other biological materials are placed into containers suitable for cryogenic storage. One such container is a pouch, much like pouches used for storing blood and other types of body fluids and cells. The pouches of stem cells are stored in a cryogenically frozen condition until they are needed. When removed from cryogenic storage, the pouch 20 as shown in FIG. 13 is placed directly into a delivery device 22 and in contact with a heating element 24 in the delivery device 22. The heating element 24 of a preferred embodiment is a thermoelectric device (TED). The thermoelectric device is activated to thaw the frozen cells in the pouch 20. A TED 24 is used instead of a standard resistance heater because the thermal output is regulated depending upon the temperature of the medium which it is trying to heat up. Consequently, as the stem cells warm up the thermal output of the TED reduces so as not to damage the stem cells, particularly those close to the walls of the pouch.

A graph 30 in FIG. 1 shows the relative power output curve 32 of the TED 24 compared to the temperature of the pouch. In particular, the graph 30 shows the relative power output, on the vertical axis 34, of the thermoelectric device in the stem cell delivery device compared to the temperature, on the horizontal axis 36 generated by the device. Temperature is shown in Celsius and the power output is shown as a percent of possible power output by the heating element. The power output curve or profile can be varied depending upon the

composition of the stem cell suspension in the pouch because different compositions of the suspension medium have different thermal conductivities.

When the stem cells in the pouch **20** have been thawed and are at a suitable temperature for injection then they are forced out of the pouch **20** by a suitable mechanical or pressure means. Means for squeezing the pouch may include pressurizing the delivery device with a disposable compressed gas cartridge or by providing rollers to squeeze the pouch, as shown in the following figures. Any means for pressing or squeezing the pouch or otherwise forcing the thawed cells from the cell container are encompassed within the scope of the present invention.

The advantages of the current invention over existing practices include that,

ancillary equipment is not required to thaw out the stem cells;

the stem cells do not have to be removed from the pouch and placed into a syringe after thawing;

the stem cells are contained in their storage pouches up until they are injected into the thereby minimizing the risk of contamination of the stem cells.

FIG. 2 shows an embodiment of the present stem cell delivery device **40**. The delivery device includes a housing **42** within which is a compartment **44** into which is placed a pouch **46** containing frozen cells. The compartment **44** has a heating element **48** abutting the pouch **46** and a squeezing or pressure means **50** to exert pressure on the pouch **46** after thawing of the frozen cells. To operate the device **40**, the pouch **46** containing the cryogenically frozen stem cells is inserted into the compartment **44** by opening a hinged top **52** of the device. The heating element **48** of a preferred embodiment is a Peltier thermoelectric device inside the delivery device that is in contact with the pouch **46** and that is operated to warm the pouch **46** and the cells therein. The squeezing apparatus **50** of the illustrated embodiment is a motor powered roller that is operable to squeeze the pouch **46** and thereby squeeze the stem cells out of the pouch. The stem cells are forced from the pouch **46** and down one or more tubes or needles that extend through openings **54** in the delivery device. After use, the pouch **46** is removed from the device **40** and the delivery device **40** kept for use again. The delivery device **40** need not be sterilizable since it does not contact the stem cells or body fluids. The delivery device **40** is reusable and may be used for sequential delivery of cells from a plurality of different pouches or for multiple sequential deliveries of cells from a single pouch.

A roller **50** is provided in the delivery device **40** to squeeze the pouch **46**. The roller **50** may be mounted in the top section of the device or may be mounted in the lower section. The roller **50** is mounted adjacent the heating element **48**. The front section **52** of the delivery device is connected to the housing **42** of the device by a hinge to permit pivoting movement of the front section **52** for opening to insert and/or remove the pouch **46** of stem cells. The front of the device **40** has two openings **54** to accommodate cell delivery tubes, which may be part of the pouch or may be selectively connected to the pouch and through which the cells are delivered to a patient or other cell receptor site.

The heating device **48** of a preferred embodiment is a Peltier device that is formed as a flat plate that is incorporated into the device below the roller **50**. The roller **50** operates to squeeze the pouch **46** against the flat plate heating element. An external power source for the heating element and for the motor that drives the roller may be provided to keep the size of the device down, or a compact power source such as a battery may be provided within the delivery device. The

motor for driving the roller may be linked to the roller by various drive means including gears, rollers, belts, or the roller may be directly driven by the motor. The delivery device may include more than one heater and may include various mechanical or pressurized delivery means positioned inside the device.

In FIG. 3, an embodiment of the stem cell delivery device **60** is shaped to fit comfortably into a user's hand. A rear section **62** provides an enclosure **64**, such as for a roller motor and/or battery as well as control circuitry, and a front upper section **66** is hinged so that the top, front part of the device is selectively openable by a user. The front end **68** includes two openings **70** formed by the upper **66** and lower sections **72** of the front end for accommodating cell pouch tubes or needles. The illustration shows the top **74** and bottom **76** halves of the device **60** separated from one another, but in use the top **74** and bottom **76** are affixed together. The hinged front section **66** pivots at a hinge **67** an angle to the body of the device and is selectively fastenable into a closed position to enclose the pouch within a pouch compartment **78** and is releasable to permit opening for insertion and removal of the pouch in the compartment **78**. Within the device is seen a roller **69** and the heating element **71**.

FIG. 4 shows the side view of the device **60** with finger recesses **80** on the bottom surface of the lower part **76** and conical front end **82** of the bottom part. The top part **74** also has a conical front end **84**, or more specifically a frusto-conical end as both conical parts **82** and **84** end in a flat front face **68**. A hinge pin **86** connects the back section **62** to the front portion **66** of the top **74** at the hinge **67**.

Turning to FIG. 5, the front end of the device **60** has the flat front face **68** at the end of the conical sections **84** and **82** of the top and bottom parts, respectively. The two openings **70** for the stem cell pouch tubes or needles are formed by recesses **70a** and **70b** in the upper and lower portions of the conical end. The front end of the device **60** is generally circular in outline when viewed from the front when assembled, although the illustration of FIG. 5 shows the top and bottom parts **74** and **76** separated for purposes of illustration. The roller heating element **71** is visible in the lower part **76**.

The side view of FIG. 6 of the device **60** is similar to the other side shown in FIG. 4, with the finger recesses **80** and the hinged top parts **66** and **62** connected by the hinge pin **86**. In this view as well, the overall shape of the device **60** is seen, wherein the conical end **82** and **84** increases in diameter from the flat front end **68** to a ridge **88**. From the ridge, the height of the lower part **76** is constant except for the finger recesses **80**, whereas the top part **74** decreases in height from the ridge **88** to the hinge **67**. From the hinge **67** rearward, the rear section **62** is of a constant height.

In FIG. 7, the top surface of the device **60** includes a flat grasping surface **90** that extends the length of the fixed rear portion **62** and from the hinge **67** to the beginning of the conical end **84** of the hinged front portion **66** at the ridge **88**. The openings **86** through which the hinge pin has been inserted for the hinge **67** are shown. The grasping surface **90** provides the user with a surface to push against when connecting the device **60** to a tube or when pushing a needle into body tissues, for example.

In the back end view of FIG. 8, the top fixed portion **62** of the rear of the device **60** has the flat grasping surface **90** across a portion of the top thereof. The flat grasping surface **90** on the front top portion **66** ramps up to the full diameter of the generally cylindrical device at the ridge **88**. The top part **74** has a flat end surface **92** and the bottom part **76** likewise has a flat end surface **94**. The roller **69** is visible inside the device.

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The unitary bottom part **76** is shown in the bottom view of FIG. **9**, including the two finger recesses **80** and the conical front section **82**. The finger recesses **80** form generally circular shapes into the cylindrical surface of the part **76**. More or fewer recesses may be provided, or some other grip enhancing feature on the part may be used instead.

FIG. **10** shows the stem cell delivery device **60** in enlarged view. The separated top and bottom parts **74** and **76** permit a view into the interior **64**, although as noted above the parts **74** and **76**. The rear section **62** includes a space in the interior **64** for motors, batteries, electronic controls and other elements of the device. In the lower part **76** below the hinge **67** is the roller **69** mounted for sliding and rotating motion to exert a squeezing force on the pouch. Tracks **96** are provided in the device **60** along which the roller **69** slides during the pouch squeezing motion. The roller **69** may be driven by a motor in the space **64** that is powered by batteries or by an external power supply. The motor to drive the roller **69** may be mounted in the rear section, below the roller **69** or some other location. Between the roller **69** and the two tube or needle openings **70** at the conical end **82** and **84** is an interior space into which a pouch containing cryogenically frozen stem cells may be inserted by opening the hinged front portion **66**. The pouch rests on the thermoelectric heating element **71** in the delivery device, either directly on the heating element **71** or on an overlying layer or covering. The cell pouch is squeezed between the roller **69** and the heating element **71**. Rotation and/or sliding motion of the roller **69** draws the pouch into the nip between the roller **69** and the heating element **71**, squeezing the contents of the pouch from the pouch opening(s), forcing the thawed cells out one or more tubes or needles connected at the pouch opening(s). The roller **69** may be provided with a covering or texture to prevent slipping on the pouch during squeezing.

FIG. **11** shows a somewhat more front view of the device **60** as compared to FIG. **10** wherein the planar or tablet shaped thermoelectric device **71** against which the frozen pouch is positioned is visible inside the hinged front section **66**. The thermoelectric device **71** extends from at or near the conical front portion **82** to beneath the roller **69**. The flat top surface of the thermoelectric device **71** permits the pouch to slide along the thermoelectric device and be drawn between the roller **69** and the back end of the thermoelectric device as the roller **69** is rotated. The pouch is drawn partially into the space **64** within the fixed rear portion **62** of the delivery device. Alternately, the roller **69** rides in tracks in the device over the pouch as the pouch remains stationary. The roller **69** may be disengaged from the squeezing position to release the pouch, or the roller may be reversed to permit removal of the pouch from the delivery device.

In FIG. **12**, an alternate embodiment includes a single needle outlet for the thawed cells. The top part of the device **100** has been removed to reveal the interior of the lower part **102**. In this embodiment, a single opening **104** is provided at the conical front end **106** where a needle **108** is attached to the pouch **110**. The pouch **110** end opposite the needle **108** fits under the roller **112**. The roller **112** is attached to two rails **114** and **116** and the rails in turn are connected to a motor **118**. The motor **118** is powered by a rechargeable battery **120** in the back of the device **100**. The battery **120** is recharged through leads **122** and **124** that connect to contact elements **126** and **128** mounted in the back end of the device **100**. The contact pins **126** and **128** are contacted by contacts of a power source to charge the battery. The power source of a preferred embodiment is a base stand that is supplied with power through a transformer connecting to AC line power, for example. The

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base stand of a preferred embodiment is similar to charging stands provided for rechargeable portable telephones and the like.

The embodiment of FIG. **12** is also shown in FIG. **13** in cross sectional view. The front top portion **130** of the device **100** is shown in the open position and a pouch **110**, also referenced **20**, is inserted into the space at the front of the device **100**. The needle **108** is connected to the pouch **20/110** extends from the device. The needle **108** is in a needle fitting **109** of the pouch. The pouch **20/110** rests on the thermo electrical heater device **24**. Power is supplied to the heater device **24** from the battery **120** when an on/off switch **134** is moved to the "on" position. The frozen cells within the pouch **20/110** are thawed or defrosted. A control circuit may be provided for ensuring that the heating of the pouch is in accordance with a thawing temperature profile.

The on/off switch **134** also supplies battery power to the motor to activate the motor **118**, which is connected to drive gear wheels **132** that engage the rails **114** and **116**. The rails **114** and **116** move the roller forward over the pouch **20/110** to squeeze the cells from the pouch and out the needle **108**. The motor **118** may be activated immediately, but preferably the operation of the motor is delayed until the cells in the pouch **20/110** are thawed sufficiently to delivery. A delay in the operation of the motor **118** may be controlled by feedback from the thermoelectric heating device, such as through use of a sensor circuit connected to between the heater and the motor. A timer may be used instead, or some other delay as well.

The delivery device **100** is provided with user controls, such as the switch **134** and possibly other controls as well as indicators for temperature, motor operation and other operating conditions. The controls and indicators may be provided either directly on the device or externally. For instance, the delivery device may have separate buttons or switches to provide user control of the heating function and squeezing function. Lights, indicators and/or display panels may be provided to indicate the operation of the heater and roller and may indicate the temperature of the pouch. A ready light may be provided. Control circuits for controlling the operation of the heater and roller and for the indicators and display are preferably included in the delivery device. The control circuit may be programmable to set a predetermined temperature profile for warming the cell pouch, and possibly for maintaining a predetermined temperature.

It is also contemplated that the heating of the pouch may commence on closing of the hinged part of the housing and thence the squeezing of the thawed cells commence upon detection of the desired delivery temperature. The control for this automatic operation may include a processor chip and associated circuitry. Control functions for the manually operated device may also include a processor controlling aspects of the heating and delivery. Sensors for detecting the presence of a pouch, the type of pouch, the type of material in the pouch, and other characteristics, may be provided.

The delivery device may be used for thawing a variety of frozen materials, including biological materials and body fluids, as well as non-biological materials.

Although other modifications and changes may be suggested by those skilled in the art, it is the intention of the inventors to embody within the patent warranted hereon all changes and modifications as reasonably and properly come within the scope of their contribution to the art.

I claim:

1. An apparatus for thawing and delivery of biological material, comprising:
 - a housing defining an interior space;
 - a thermoelectric heating element mounted in said interior space and having a heating surface configured to receive a biological material container;
 - a squeezing apparatus mounted in said interior space and operable to exert a squeezing force on a biological material container received at the heating surface of said thermoelectric heating element; and
 - a control for applying power to said thermoelectric heating element so as to warm biological material within the biological material container and to operate said squeezing apparatus so as to deliver the warmed biological material from the biological material container;
 wherein said squeezing apparatus is a roller pressing the biological material container against the thermoelectric heating device and operable to squeeze biological material from the container.
2. An apparatus for thawing and delivery of biological material, comprising:
 - a housing defining an interior space, the housing defining a compartment within the housing, the housing being configured to enclose a container of biological material within the compartment when in a closed condition;
 - a thermoelectric heating element mounted in said interior space and having a heating surface configured to receive a biological material container;
 - a squeezing apparatus mounted in said interior space and operable to exert a squeezing force on a biological material container received at the heating surface of said thermoelectric heating element, the squeezing apparatus being operable to exert the squeezing force while the housing remains in the closed condition; and
 - a control for applying power to said thermoelectric heating element so as to warm biological material within the biological material container and to operate said squeezing apparatus so as to deliver the warmed biological material from the biological material container;
 wherein said housing includes a first portion defining a fixed housing portion and a second portion having a selectively openable portion to provide access to the heating surface by a biological material container.
3. An apparatus for thawing and delivery of biological material, comprising:
 - a housing defining an interior space, the housing defining a compartment within the housing, the housing being configured to enclose a container of biological material within the compartment when in a closed condition;
 - a thermoelectric heating element mounted in said interior space and having a heating surface configured to receive a biological material container;
 - a squeezing apparatus mounted in said interior space and operable to exert a squeezing force on a biological material container received at the heating surface of said thermoelectric heating element, the squeezing apparatus being operable to exert the squeezing force while the housing remains in the closed condition;
 - a control for applying power to said thermoelectric heating element so as to warm biological material within the biological material container and to operate said squeezing apparatus so as to deliver the warmed biological material from the biological material container; and
 - a rechargeable battery within the housing connected to supply power to at least one of said thermoelectric heating element and said squeezing apparatus.

4. An apparatus for thawing and delivery of biological material, comprising:
 - a housing defining an interior space, the housing defining a compartment within the housing, the housing being configured to enclose a container of biological material within the compartment when in a closed condition;
 - a thermoelectric heating element mounted in said interior space and having a heating surface configured to receive a biological material container;
 - a squeezing apparatus mounted in said interior space and operable to exert a squeezing force on a biological material container received at the heating surface of said thermoelectric heating element, the squeezing apparatus being operable to exert the squeezing force while the housing remains in the closed condition;
 - a control for applying power to said thermoelectric heating element so as to warm biological material within the biological material container and to operate said squeezing apparatus so as to deliver the warmed biological material from the biological material container; and
 - a hand grip surface on an outside of the housing including finger notches formed into the housing, the housing being configured for holding in a user's hand.
5. An apparatus for thawing and delivery of biological material, comprising:
 - a housing defining an interior space, the housing defining a compartment within the housing, the housing being configured to enclose a container of biological material within the compartment when in a closed condition;
 - a thermoelectric heating element mounted in said interior space and having a heating surface configured to receive a biological material container;
 - a squeezing apparatus mounted in said interior space and operable to exert a squeezing force on a biological material container received at the heating surface of said thermoelectric heating element, the squeezing apparatus being operable to exert the squeezing force while the housing remains in the closed condition;
 - a control for applying power to said thermoelectric heating element so as to warm biological material within the biological material container and to operate said squeezing apparatus so as to deliver the warmed biological material from the biological material container; and
 - contacts on said housing for receiving recharging power.
6. A method for delivering frozen biological materials, comprising the steps of:
 - inserting a container of frozen biological materials into an enclosed compartment within a delivery device in thermal contact with a heating element;
 - applying a heat to the container of frozen biological materials to thaw the biological materials;
 - applying a squeezing force on the container while the container is in thermal contact with the heating element; and
 - delivering thawed biological materials from the container while the container of biological materials remains within the enclosed compartment;
 wherein said step of inserting a container includes:
 - pivotably opening a portion of a housing of a delivery device;
 - inserting the container into the delivery device at the open portion; and
 - pivotably closing the portion of the housing to enclose the container within the delivery device.

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7. A method for delivering frozen biological materials, comprising the steps of:
- inserting a container of frozen biological materials into a delivery device in thermal contact with a heating element;
 - applying a heat to the container of frozen biological materials to thaw the biological materials;
 - applying a squeezing force on the container while the container is in thermal contact with the heating element; and
 - delivering thawed biological materials from the container;
- wherein said container is inserted into a handheld delivery device that encloses the container, the heating element, and the squeezing apparatus.
8. An apparatus for delivery of frozen biological material, comprising:
- a housing having a conical first end and a second end, said conical first end defining a delivery opening;
 - a pivotably openable portion of the housing;

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- a thermoelectric heating element having a flat heating surface and mounted within an openable portion of the housing, the flat heating surface being configured to receive a pouch of frozen biological material and being operable to apply heat to the pouch;
- a roller mounted within the housing and disposed to receive a pouch of frozen biological material between said roller and said heating element;
- a motor operably connected to said roller and operable to rotate said roller so as to cause the roller to squeeze the pouch of biological material; and
- a delivery conduit extending from said delivery opening of said conical first end of said housing through which the biological material is delivered upon application of squeezing force by the roller on the thawed biological material in the pouch.

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